

TUBERCULOSIS SURVEILLANCE AND CONTROL IN GERMANY – AN APPLICATION OF THE BERLIN DECLARATION MONITORING AND EVALUATION FRAMEWORK

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Background: In 2007, the ‘Berlin Declaration on Tuberculosis’ (BD) was signed by the Ministers of the WHO European Region Member States (MS) to address the re-emerging threat of tuberculosis (TB) by fully implementing the Stop TB strategy. WHO Euro developed a Monitoring and Evaluation (M&E) Framework using programmatic and epidemiological indicators to follow-up the BD from 2013 onwards. Ahead of this, we explored the Framework performance for Germany, a low TB incidence country.

Methods: We selected from a surveillance perspective on five country-specific indicators asked for all MS. Information sources included guidelines, notification data and laboratory quality assurance results.

Results: As to national TB guidelines (indicator 1.1.1), up-to-date guidance documents are available. Regarding external quality assurance (3.2) proficiency testing confirms high quality of culture and drug-susceptibility testing. M/XDR-TB prevention and control is reflected by a 1.7% MDR-TB rate in 2010 with decreasing tendency (4.1.2). As to treatment success (5), the WHO target of 85% is reached for all age groups except the elderly ≥ 60 years. Germany disposes of an electronic case-based surveillance providing evidence for TB policy and practices (5.2.2).

Conclusions: The selected M&E Framework indicators proved well applicable to a low-incidence country. The results show no specific gaps in TB surveillance and control in Germany.

Keywords: tuberculosis, Berlin Declaration (BD), monitoring, evaluation, framework, Germany

Background

In October 2007, a Ministerial Forum was organized by WHO-Euro and the German Ministry of Health in order to discuss challenges and problems in tuberculosis control in the WHO Europe region. As a result of this meeting, the health ministers of the Member States adopted the Berlin Declaration (BD) on Tuberculosis [1], hereby addressing the re-emerging threat of tuberculosis to health security in the region, acknowledging the need and stating their commitment for action. Both by high and low burden countries, areas of concern were identified where steps need to be taken to fully implement the Stop TB strategy [2]. It was also agreed upon the biennial evaluation of the progress and obstacles [3]. To follow up the countries’ efforts and achievements in the implementation process of the BD, an international task force was established under the leadership of the WHO Regional Office for Europe to prepare the respective monitoring and evaluation (M&E) framework. Meanwhile, the framework has become an integrated part of the annual surveillance and monitoring

report produced by WHO’s Regional Office and the European Centre for Disease Prevention and Control (ECDC) [4], and the countries and National TB Programme managers are highly encouraged to use the document.

Germany is one of the region’s countries with a low TB incidence of 5.3 cases/100,000 population, corresponding to an absolute case number of 4330 in 2010 [5] (2011: 5.3/100,000; 4299 cases [6]) (*Fig. 1*).

Although experiencing a longstanding declining trend, the tuberculosis incidence in the last 2 years has markedly less decreased than in previous years, mainly due to a slight increase in foreign citizens. Hence, one can assume that Germany is approaching a steady state – similar to other Western European countries [4]. Furthermore, since 2009, a slight raise in tuberculosis incidence rates can be observed in children (with corresponding case numbers of 142 TB cases in 2009, 158 in 2010). This might be a sign of a changing trend, as pediatric tuberculosis (which is usually primary tuberculosis) indicates recent infection [5].

The aim of our investigation was the exploration of the performance of the M&E framework for Germany by ap-

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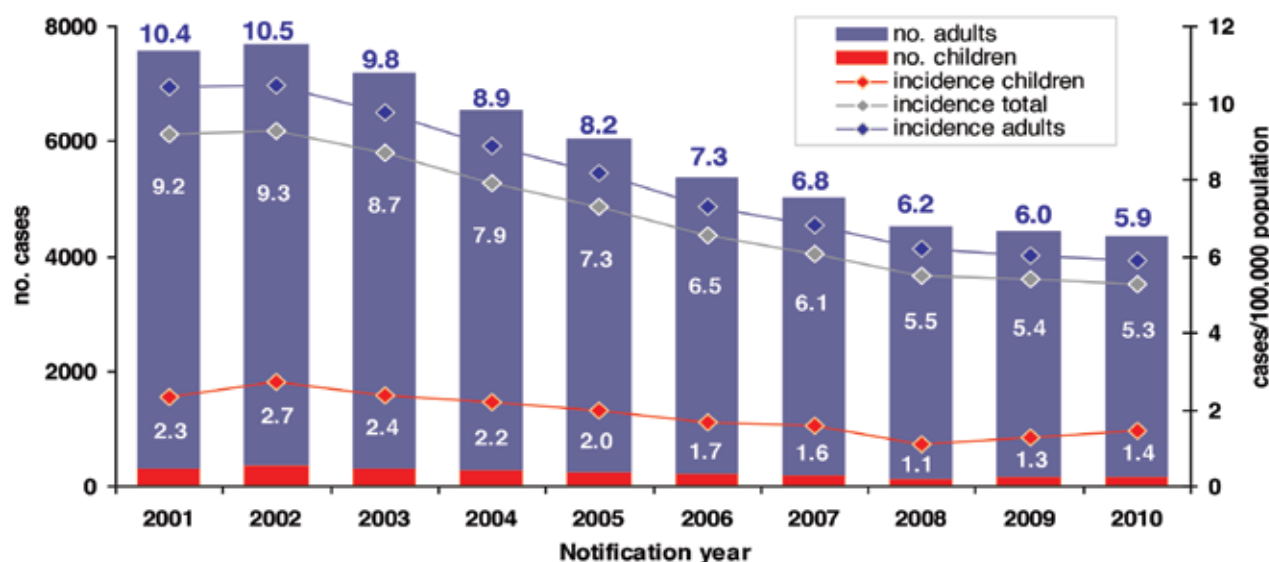


Fig. 1. Number of TB notifications and TB incidence in Germany for adults and children, 2002–2010 (by August 1, 2011)

plying a selected set of M&E framework indicators. The results shown have been presented at the 6th Scientific Symposium of the Koch–Metschnikow-Forum on the occasion of World Tuberculosis Day 2011.

Methods

In the M&E framework, priorities and commitments are grouped and expressed as seven expected outcomes addressing the following aspects: (1) health system strengthening, (2) financing, (3) use and development of tools, diagnostics, drugs, and vaccines, (4) M/XDR-TB, HIV and other challenges, (5) DOTS, (6) political priority and attention, and (7) engagement of all health care providers, patients and civil society organisations. Each of these outcomes has a corresponding set of outputs. Most outcomes have one related outcome indicator and each output has an average of one or two output indicators (for further details see [4]).

From the perspective of the Robert Koch Institute (RKI), which is the national public health institute responsible for TB surveillance and control, we selected five M&E framework outcome and output indicators from a surveillance point of view, focussing on country-specific indicators asked for all 53 MS.

Information sources included available national tuberculosis guidelines, national tuberculosis notification data, and results of external quality assurance (EQA) of laboratories:

In Germany, clinical tuberculosis guidance documents are developed and regularly updated by the German Central Committee against Tuberculosis (DZK) in close cooperation with the medical societies for lung health in adults and children, the RKI, and the Public Health Service. The RKI is responsible for TB surveillance and develops respective manuals for TB notification and case definitions.

Guidelines and quality standards in mycobacteriological diagnostic are developed and published by the German Society of Hygiene and Microbiology (DGHM).

With the implementation of the new ‘Protection against Infection Act’ in 2001 in Germany [8], the TB surveillance system was updated in agreement with international standards [4]. For each notified case, anonymized case-based data are submitted electronically by the local health authority via the state health department of each federal state to the national database at the RKI. Data can be continuously updated and contain demographic information about the patient, information about the disease, prior treatment, treatment outcome, and diagnostic results. Data are collected with a special software (SurvNet@rki) [9]. All analyses were performed using Excel (version 11, Microsoft Corporation, Redmond, Washington, USA) and Stata (version 12.1, StataCorp LP, Texas, USA).

Results of EQA of laboratories were received from the website of INSTAND e.V./Düsseldorf, which is a non-profit society for the organization of EQA in medical laboratories [7]. The performance of EQA for laboratory diagnostics for mycobacteria (microscopy, culture, DST) was organized by the National Reference Laboratory for Mycobacteria in Borstel.

Results

The first M&E framework outcome addresses ‘Health Systems strengthened by integrating TB care delivery in general health service,’ with the corresponding outcome indicator ‘MS have a national health strategy where TB prevention and control are embedded.’ In this respect, we assessed indicator 1.1.1, which asks for the availability of ‘national guidelines for TB care, adjusted in line with the international standards.’ For Germany, up-to-date guid-

Table 1. Proficiency testing of laboratory diagnostics for mycobacteria; organized by INSTAND e.V./Düsseldorf in collaboration with the National Reference Laboratory in Borstel: Results of the External Quality Assurance (EQA) in spring (I) and autumn (II) 2011 [7]

Method	WHO target	EQA results		Proportion of labs receiving EQA certificate		Number of participating labs (N)	
		I	II	I	II	I	II
Year 2011							
Microscopy	No high false positive (FP) and no high false negative (FN)	Low FP and low FN	FP should be improved	97.6%	92.0%	254	238
Culture	Sensitivity >90% (in smear+)	99.5%	99.4%	99.5%	99.4%	189	181
Drug susceptibility testing (DST)	≥95% DST agreement with NRL for Isoniazid and Rifampicin	WHO target achieved	WHO target achieved	97.6%	98.6%	84	72

ance documents are available covering all aspects for TB care, that is infection control [10], contact tracing [11], screening and treatment of persons with latent TB infection [11–13], TB treatment in adults and children [11, 12], directly observed therapy [14], surveillance [15], and quality assured bacteriological diagnostics [16].

Regarding the expected outcome ‘Available tools used, and new diagnostics, drugs and vaccines developed through basic research and product development,’ MS are expected to ‘routinely use effective diagnostic and treatment tools.’ We focused on indicator 3.2 ‘quality assured bacterial culture and drug susceptibility testing ensured.’ The summarized results of the external quality assurance proficiency testings [7] confirm altogether the high quality of culture and drug susceptibility testing (*Table 1*).

As to the expected outcome ‘M/XDR TB, HIV-related TB and other challenges addressed, particularly in vulnerable and hard-to-reach populations,’ the framework asks for the ‘number of MS that have data and specific policy/strategy on M/XDR-TB, HIV etc. in their national health strategies.’ Here, we put the emphasis from our surveil-

lance point of view on ‘MDR- and XDR-TB prevention and control ensured’ by looking at indicator 4.1.2, which expects a decrease of the percentage of MDR-TB among all TB cases. *Table 2* shows numbers and proportions of MDR-TB observed among notified TB patients with available information on DST results in the recent years, with an MDR-TB rate of 1.7% among notified cases in 2010 and a decreasing tendency (results published elsewhere [17]).

As to the outcome ‘Directly observed treatment short course (DOTS) expanded and enhanced,’ we applied outcome indicator 5 ‘Proportion of successfully treated cases among laboratory confirmed new TB patients’ to the German situation. Germany reaches the WHO target of 85% for all age groups (for all notified TB cases with available information on treatment outcome) with the exception of the elderly ≥ 60 years (*Fig. 2*).

The output indicator 5.2 asks MS for ‘Evidence base for TB policy and practices through enhanced TB surveillance and monitoring’ by use of ‘...electronic case-based surveillance at the national level’ (as stated in indicator 5.2.2). Germany does meet these requirements as it dis-

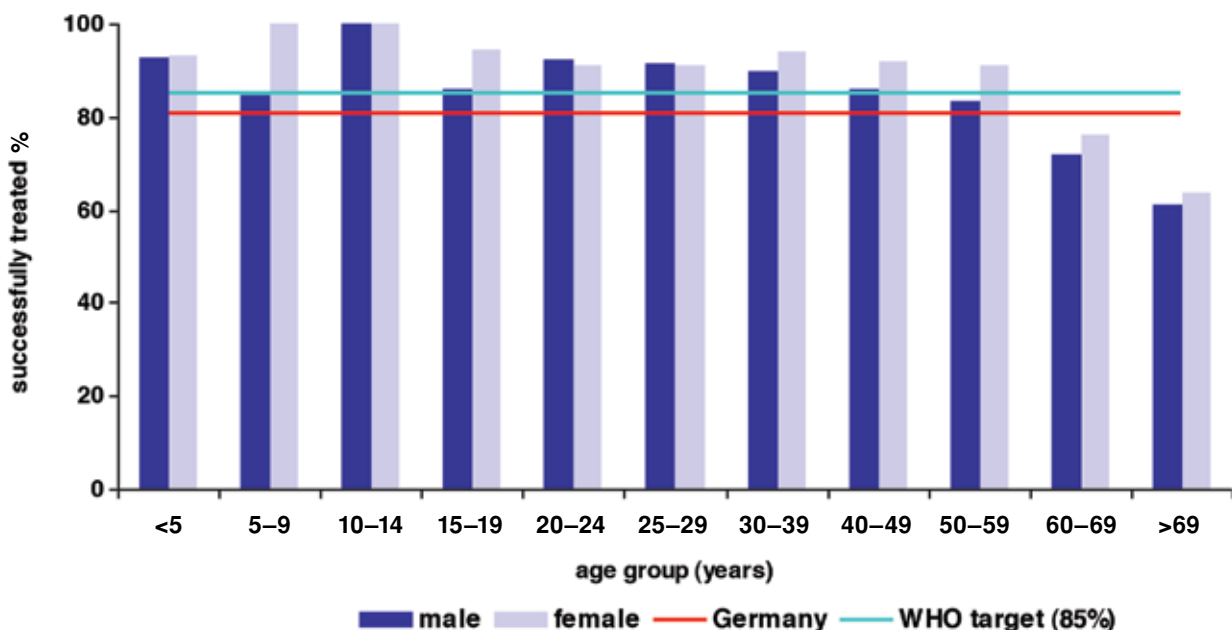
**Fig. 2.** Successful treatment outcome in Germany 2009 (for all notified TB cases with available information on treatment outcome) by age group and sex (N=4020) [5]

Table 2. Numbers and proportions of MDR-TB cases in Germany, 2002–2010 [5]

Year of notification	Number of MDR-TB patients (<i>N</i>) [Number of TB patients with DST information available]	% MDR-TB among all TB notifications
2002	97 [4,692]	2.1
2003	95 [4,473]	2.1
2004	99 [4,074]	2.4
2005	106 [3,898]	2.7
2006	82 [3,631]	2.3
2007	69 [3,323]	2.1
2008	49 [3,039]	1.6
2009	63 [3,036]	2.1
2010	48 [2,747]	1.7

poses of an electronic case-based surveillance system since 2001 [9]. An extensive epidemiological surveillance report is published yearly [5].

Discussion and conclusions

The M&E Framework for the Berlin Declaration ‘... has been designed for the countries and their National Tuberculosis Control Programs to monitor their efforts to implement the Berlin Declaration....’ [4]. With our investigation, we piloted the new M&E framework in a low-incidence country.

We focused on indicators particularly relevant from our perspective of the national public health institute, and naturally concentrated on indicators asked from all MS (as some indicators address the situation in high priority countries only).

Hereby, we did not cover other areas of concern, such as human resource capacity (e.g. indicator 1.2), funding strategies (indicator 2), political commitment (indicator 6), and general engagement and collaboration (indicator 7). Although acknowledging the importance of these indicators for the Europe region, these aspects are predominantly beyond the scope of the RKI as the German national contact point of a federal state, where the responsibility for the implementation of health care lays within the 16 different states.

Although Germany does not have one overarching TB control strategy document, up-to-date guidance documents are available covering all aspects for TB care. However, the availability of guidance documents alone does not allow any assessment of the degree of implementation, the quality of TB care, and the education and training level of care-givers. Additional evidence is therefore needed and part of ongoing and planned research in this respect.

The high-quality standards in mycobacteriological diagnostics reflect that in Germany quality assurance and sufficient laboratory capacities and resources are highly

acknowledged as an important prerequisite for a well-functioning TB control.

When interpreting the low proportions of MDR-TB and decreasing MDR-TB notification rates, besides small case numbers we have to take into account that MDR-TB in Germany is particularly frequent in patients originating from former Soviet Union States [5] and thus depending on migration flows and patterns.

In terms of treatment success, it is to note that more than a third of our TB patients, especially in the German-born population, do belong to the age group aged 60 years and older [18]. Thus, due to co-morbidity and a higher mortality of elderly TB patients an overall target of 85% as set by WHO seems to be hard to reach in the near future.

As required, Germany has implemented an electronic case-based surveillance, allowing for detailed epidemiological analysis and herewith providing evidence for TB policy and practices.

However, with TB incidence approaching a steady state and a slight increase of childhood TB cases, we are aware that the application of the indicators described may not reflect the current and future developments sufficiently. Further epidemiological in-depth study of specific population groups and additional insights in the implementation of guidelines are necessary to identify needs and gaps and to generate evidence for adapting and optimizing TB control strategies appropriately. In order to better understand the country-specific epidemiological situation, the RKI has initiated and/or is cooperating in studies and projects, which will provide and add important information on vulnerable populations such as migrants, prisoners, children and the elderly, on current epidemiological trends, drug resistance, quality of treatment, and ways to improve treatment outcome monitoring. The risk of waning expertise is high in low-incidence countries, and sustained awareness needs to be maintained.

In summary, the selected M&E framework indicators proved well applicable to a low-incidence country and the presented results show no specific gaps in TB surveillance and control in Germany.

We experienced the M&E framework as a valuable tool not only to support countries in assessing and documenting their implementation progress of the Berlin Declaration, but also to encourage and inspire them to further explore identified country-specific issues and challenges.

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References

1. The Berlin Declaration. http://www.euro.who.int/__data/assets/pdf_file/0008/68183/E90833.pdf
2. World Health Organization. The Stop TB Strategy. Building on and enhancing DOTS to meet the TB-related Millenium Development Goals. World Health Organization 2006. WHO/HTM/TB/2006.368 (http://whqlibdoc.who.int/hq/2006/WHO_HTM_STB_2006.368_eng.pdf)
3. Castell S, Hauer B, Manissero D, Ulrichs T, Zaleskis R, Loddenkemper R.: Berlin Declaration on Tuberculosis: High Level Follow-Up of High Priority Countries for TB Control in the WHO-EURO Region 'Double Trouble or Double Success? Bringing Together Diseases and Programs'- ein Symposiumsbericht. *Pneumologie* 64, 422–429 (2010)
4. European Centre for Disease Prevention and Control/WHO Regional Office for Europe. Tuberculosis surveillance and monitoring in Europe 2012. Stockholm: European Centre for Disease Prevention and Control, 2012.
5. Robert Koch-Institut. RKI-Bericht zur Epidemiologie der Tuberkulose in Deutschland für 2010. Robert Koch-Institut (RKI) Berlin, Germany 2012 http://www.rki.de/DE/Content/InfAZ/T/Tuberkulose/Download/TB2010.pdf?__blob=publicationFile
6. Robert Koch Institut. Infektionsepidemiologisches Jahrbuch meldepflichtiger Krankheiten für 2011. Berlin März 2012
7. <http://www.instandev.de/index.php?id=425>
8. Act on the prevention and control of infectious diseases in man (Protection against infection act). Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz IfSG) <http://bundesrecht.juris.de/ifsg/index.html>
9. Krause G, Altmann D, Faensen D, Porten K, Benzler J, Pfoch T et al.: SurvNet electronic surveillance system for infectious disease outbreaks, Germany. *Emerg Infect Dis* 13, 1548–1555 (2007)
10. Ziegler R, Just HM, Castell S, Diel R, Gastmeier P, Haas W, Hauer B, Loytved G, Mielke M, Moser I, Nienhaus A, Richter E, Rüden H, Rüsche-Gerdes S, Schaberg T, Wischniewski N, Loddenkemper R.: Tuberculosis infection control – recommendations of the DZK [Article in German] *Pneumologie* 66, 269–282 (2012)
11. Diel R, Loytved G, Nienhaus A, Castell S, Detjen A, Geerdes-Fenge H, Haas W, Hauer B, Königstein B, Maffei D, Magdorf K, Priwitzer M, Zellweger J-P, Loddenkemper R: New recommendations for contact tracing in tuberculosis German Central Committee against tuberculosis [Article in German]. *Pneumologie* 65, 359–378 (2011)
12. Schaberg T, Bauer T, Castell S, Dahlhoff K, Detjen A, Diel R, Greinert U, Hauer B, Lange C, Magdorf K, Loddenkemper R.: Recommendations for therapy, chemoprevention and chemoprophylaxis of tuberculosis in adults and children [Article in German]. *Pneumologie* 66, 133–171 (2012)
13. Diel R, Hauer B, Loddenkemper R, Manger B, Krüger K.: Recommendations for tuberculosis screening before initiation of TNF-alpha inhibitor treatment in rheumatic diseases [Article in German]. *Pneumologie* 63(6), 329–334 (2009)
14. Arbeitskreis Tuberkulose im Fachausschuss Infektionsschutz des Berufsverbandes der Ärztinnen und Ärzte des OGD. Sicherung des Behandlungserfolges bei Tuberkulose. *Epidemiologisches Bulletin* 11, 93–95 (2012)
15. Falldefinitionen des Robert Koch-Instituts zur Übermittlung von Erkrankungs- oder Todesfällen und Nachweisen von Krankheitserregern. Robert Koch-Institut, Berlin 2007
16. Mikrobiologisch-infektiologische Qualitätsstandards (MIQ) 5 Tuberkulose, Mykobakteriose, 2. Auflage 2010, Elsevier Urban & Fischer Verlag
17. Fiebig L, Brodhun B, Hauer B, Altmann D, Haas W.: Tuberculosis in Germany: trends and trend indicators. Abstract Book 42nd World Conference on Lung Health of the International Union Against Tuberculosis and Lung Diseases (The Union), Lille France 2011
18. Hauer B, Brodhun B, Altmann D, Fiebig L, Loddenkemper R, Haas W.: Tuberculosis in the elderly in Germany. *Eur Respir J* 38(2), 467–470 (2011)